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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,164	07/25/2005	Hermanus Carolus Catherina Karel Bakel Van	101384-1 US	2743

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EXAMINER

OH, TAYLOR V

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,164

Applicant(s)

BAKEL VAN ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/05 & 10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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The Status of Claims

Claims 1-11 are pending.

Claims 1-11 are rejected.

DETAILED ACTION

1. In the preliminary amendment, claims 1-11 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/NL03/00435 filed on 06/12/2003, which has a foreign priority document, EP-02100715.8 filed on 06/17/2002.

Drawings

3. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DMF and N-methylpyrrolidone as a catalyst does not reasonably provide enablement for all kinds of catalysts known in the art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include

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all kinds of catalysts unrelated to the claimed invention commensurate in scope with these claims.

Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

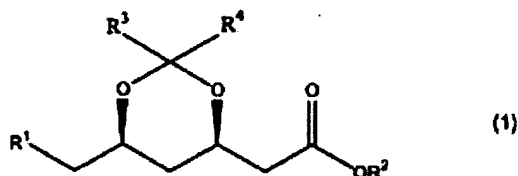
Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breath of the claims.

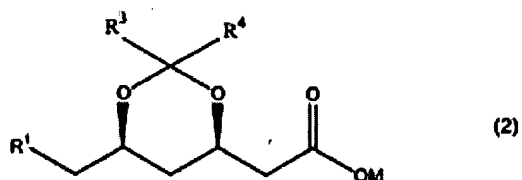
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The Nature of the Invention

The nature of the invention in claim 1 is the process for preparing an ester of formula (1),



wherein R¹ represents a leaving group, CN, OH or a COOR⁵ group, R³ and R⁴ each independently represent a 1-3 C alkyl group, and COOR² [[R²]] and COOR³ [[R³]] each independently represent an ester residue, comprising contacting wherein the corresponding salt of [[with]] formula (2),



wherein M represents H or an alkali ~~or alkaline earth (earth)~~ metal ~~in an inert solvent is~~ contacted with an acid chloride forming agent in an inert solvent to form the corresponding acid chloride, and contacting the acid chloride ~~is contacted~~ with an alcohol of [[with]] formula R²OH in the presence of N-methyl-morpholine.

The State of the Prior Art

The states of the prior art are described as followed:

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In the process according to the invention the compound of formula (3) can for example be esterified to form the corresponding tert. butyl ester using the following methods, which in general are described in literature:

reaction with isobutene and strong acid, for example paratoluene sulphonic acid (pTS), sulphuric acid or a strongly acidic ion exchanger (US-A-3325466);

reaction via the acid chloride and t-butanol, under the influence of a base, for example triethylamine (Et₃N), dimethylamino pyridine (DMAP). The acid chloride can be prepared with the aid of for example SOCl₂, POCl₃, (COCl)₂

and catalyzed by for example dimethyl formamide (DMF) (J. Org. Chem. 35 2428 (1970));

reaction via the acid chloride with Li-t-butanolate (Org. Synth. 51 96 (1971));

transesterification with t-butyl acetate under the influence of a strong acid (Z. Chem. 12(7) 264 (1972));

reaction of the salt with t-butyl bromide, preferably in DMF, dimethyl acetamide (DMAA), 1-methyl-2-pyrrolidinone (NMP) and using a phase transfer catalyst (PTC) (Tetr. Let. 34 (48) 7409 (1993));

reaction of the acid with t-butanol, 1,3-dicyclohexyl carbodiimide (DCC) and DMAP (Synth. Comm. 9, 542 (1979));

reaction of the acid with t-butyl-trichloro acetamidate (Tetr. Let. 36, 1657 (1998));

reaction of the salt with carboxyl diimidazole (CDI) and t-butanol;

reaction of the acid with phthaloyl chloride and t-butanol under the influence of DMAP or N-methyl-morpholin (NMM) (Bull. Chem. Soc. Japan 52 (7) 1889 (1979));

reaction of the salt with di-tert. butyl dicarbonate, DMAP and t-butanol (Synthesis 1063 (1994));

reaction of the acid with cyanuric chloride and pyridine or triethylamine (Org Process R&D 3, 172 (1989); Heterocycles 31 11, 2055 (1990)).

As the prior art have been discussed in the above, there is no conclusive data that all the kinds of catalyst in the process of forming acid chloride would work to produce the final desired product.

The predictability or lack thereof in the art

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that any catalyst would not work on the claimed process in the same way as those catalysts such as DMF and N-methylpyrrolidone disclosed in the specification.

According to T.P.Hilditch, the author of the "Catalytic Processes in Applied Chemistry" (see pages Xiii-XV, 1929), there is a definitive reason for an unpredictable aspect of the catalysts in the art of organic chemistry. T.P.Hilditch expressly teaches that any catalyst would not work for any kind of the reaction process; for example, the specific catalysts such as mineral acids, acetic anhydride, sulfuric acid, calcium chloride, and etc can be used for the esterification; on the other hand, this same kind of catalyst will not apply to the other types of the reaction process in the followings: the chlorination of organic compounds, the oxidation of organic compounds, the process for rubber accelerators, the hydrogenation or the dehydrogenation processes, ammonia synthesis, ammonia oxidation, sulfuric acid manufacture, and etc. (see pages Xiii-XV).

Furthermore, the specification of the claimed invention does support the very idea of the unpredictable aspect of the catalysts by disclosing the following specific, workable catalyst for the epoxidation, not all kinds of the catalyst known in the art.

Moreover, the case law advocates that the catalyst compositions represent an unpredictable aspect in the art of organic chemistry. See Exparte Sizto, 9 USPQ2d 2081 (Bd. Of App. And Inter. March 1988). Therefore, the use of a generic phrase "a catalyst" can not ensure to form the desired claimed product in a good yield.

The amount of direction or guidance present

The direction present in the instant specification is that not any catalyst can be led to the formation of the desired product. According to the specification, it is silent as to how any catalyst can be led to the formation of the desired product and fails to provide guidance as to whether any catalyst is sufficient enough to allow to form the desired product in sufficient quantities; the specification fails to provide a correlation between the claimed process of the invention and the functional language of any catalyst.

The presence or absence of working examples

There are only 2 working example using the NMP catalyst for producing the desired compound in the specification. This can not be the representatives for all the catalysts which would work for the claimed process. Thus, the specification fails to provide enough working examples as to how the other types of catalysts can be resulted in the claimed products, i.e. again, there is no correlation between the functional language of any catalyst and the desired final product.

The breadth of the claims

The breadth of the claims is that any catalyst would work on the claimed process in the same way as the disclosed catalyst without considering the affect or impact of the different catalysts on the starting compound, thereby affecting the yield of the desired final product.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine which one of the catalysts would be capable of forming the desired

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product and would furthermore then have to determine which one of the catalysts would not be resulted in the claimed desired compounds in a sufficient quantity.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which catalyst can be employed to produce the desired claimed compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "an ester residue" is recited. This expression is vague and indefinite because the skilled artisan in the art is unable to figure out whether the ester residue may be an ester, an acid, or an alcohol. Therefore, an appropriate correction is required.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

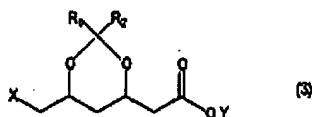
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Kooistra et al (WO 02/06266 A1).

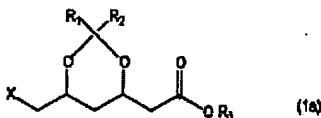
Kooistra et al discloses the process for preparing 2-(6-substituted-1,3-dioxane-4-yl) acetic acid derivatives in the following description.

The salts (acids) obtained are novel. The invention therefore
5 also relates to these products of formula 3



where X stands for a halogen, in particular Cl, Br or I, a tosylate or mesylate
10 group, an acyloxy group with 3-10 carbon atoms, or a nitro-substituted benzene sulphonyl group and Y stands for H, an alkaline (earth) metal, or a substituted or unsubstituted ammonium group.

The resulting salt of formula 3 can subsequently be converted
15 into the corresponding t-butyl ester (formula 1a with R3 = t-butyl), in a way known per se.



In the process according to the invention the compound of formula (3) can for example be esterified to form the corresponding tert. butyl ester using the following methods, which in general are described in literature:

(see page 5 , lines 5-20)

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reaction of the acid with phthaloyl chloride and t-butanol under the influence of DMAP or N-methylmorpholine (NMM) (Bull. Chem. Soc. Japan 52 (7) 1989 (1979));

(see page 6 , lines 15-17)

The resulting t-butyl ester of 2-(6-substituted-1,3-dioxane-4-yl)acetic acid can subsequently be converted into the 2-(6-hydroxymethyl-1,3-dioxane-4-yl)acetic acid, for example as described in US-A-5594153 or in EP-A-1024139, in the presence of a tetraalkyl ammonium halogenide and/or a carboxylic acid in the salt, via conversion into a compound of formula 1a with $R_1 = t\text{-butyl}$ and $X = \text{an acyloxy}$, for example an acetoxy group. The acyloxy group can subsequently be converted via solvolysis, in a way otherwise generally known, to a hydroxyl group. The solvolysis can be performed using a base (Na_2CO_3 , K_2CO_3 , or sodium methanolate in methanol), optionally by simultaneous distillation of the methyl acetate formed.

(see page 6 ,lines 22-31).


This is identical with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Taylor Victor Oh, MSD, LAC
Primary Examiner
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10/27/06